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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,071	12/29/2003	Paul A. Barsanti	19814.004	8570

27476 7590 02/08/2008

NOVARTIS VACCINES AND DIAGNOSTICS INC.
INTELLECTUAL PROPERTY R338
P.O. BOX 8097
Emeryville, CA 94662-8097

EXAMINER	
SNYDER, STUART	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
02/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,071	BARSANTI ET AL.	
	Examiner	Art Unit	
	Stuart W. Snyder	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3 and 75-112* is/are pending in the application.

4a) Of the above claim(s) *111-112* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3 and 75-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Acknowledgement is made of cancellation of claims 1, 4-23, 25-28 and 30-74, amendment of claim 2 and new claims 75-112. Claims 2-3 and 75-112 are pending and examined herein.

Claim Rejections - 35 USC § 102

2. Rejection of claim 1 under 35 USC § 102 is moot and **withdrawn** in view of cancellation of the claim.

Claim Rejections - 35 USC § 103

3. Rejection of claims 1-3 and 63 under 35 USC § 103 is moot and **withdrawn** in view of cancellation of the claim and Applicants' arguments filed 11/30/2007.

Claim Rejections - 35 USC § 112

4. Claims 2-3 and 75-112 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specifically recited examples of Tables 1-3 of the specification for the compositions used *in vitro* with an HCV model, does not reasonably provide enablement for the broadest interpretation of the base and subsequent claims, e.g., use as a vaccine adjuvant with for treatment and prevention of cancers and microbes *in vivo.* The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Use of vaccine adjuvants is still an empirical art requiring experimentation to optimize antigen concentration, adjuvant

concentration, routes of administration, etc. and must be performed for each antigen/antigen/vaccinee species. Altman discusses the hope for a universal vaccine formulation, in terms of optimal combinations of vehicles (which includes adjuvants, see p313), and notes that a universal vaccine formulation will not be available in the near future. Simply, examination of the vast literature in this area reveals that for almost every vehicle (including adjuvant) found to be effective with a given antigen and a certain vaccination schedule, a contrasting report documents the lack of activity by the same immunomodifier(s) with another antigen or under slightly different conditions (Concluding remarks page 338). Aucouturier teaches that there are no universal adjuvants. Adjuvants must be adapted according to several criteria, such as the target species, the antigen, the type of immune response, inter alia (abstract, conclusion). East provides that the mechanisms by which adjuvants promote the immune response are poorly understood. Indeed, East teaches that studies involving adjuvants still do not allow the skilled artisan to predict with confidence which adjuvant will work, particularly with recombinant vaccines, as the author directs that it is clear that, much more work needs to be done on the nature of immunopotentiation and adjuvant action before the skilled artisan can, with confidence, combine new generation antigens with appropriate adjuvants to make successful vaccines. (See Introduction p. 2, Conclusion, p. 17). Edelman teaches that adjuvant use remains largely empiric. Edelman also teaches that adjuvant effects are unpredictable, with adjuvant results arising from a complex interplay between

route of administration, timing of inoculations, antigen dose, host species, and within-species genetic variation. Thus, Edelman teaches that as a consequence of these variables, antigens are best matched with adjuvants by means of a trial by error process of iterative experiments. McElrath teaches that the success of an adjuvant in clinical studies may not always be predictable from animal studies, and that adjuvant properties may differ according to the immunogen with which the adjuvant is formulated (See, e.g., Summary p 283). Wiilson provides an example of trial with several adjuvants, showing that components known as an adjuvant (e.g., it has been effective as adjuvant in another setting), including the famous aluminum hydroxide used in human vaccination, is not necessarily effective as an adjuvant in another setting (abstract). Thus, a skilled artisan would be required to perform undue experimentation to practice the full scope of the invention.

Conclusion

5. No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

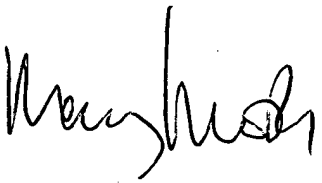
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stuart W Snyder
Examiner
Art Unit 1648

SWS



MARY E. MOSHER, PH.D.
PRIMARY EXAMINER